PUMA BIOTECHNOLOGY, INC.
Form 10-Q
May 10, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2016

OR

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File Number: 001-35703

PUMA BIOTECHNOLOGY, INC.

(Exact name of registrant as specified in its charter)

Delaware	77-0683487
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

10880 Wilshire Boulevard, Suite 2150, Los Angeles, CA 90024

(Address of principal executive offices) (Zip code)

(424) 248-6500

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨.

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer x	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date. 32,493,092 shares of Common Stock, par value $0.0001 per share, were outstanding as of May 3, 2016.

PUMA BIOTECHNOLOGY, INC.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward looking. These forward-looking statements include, but are not limited to, statements about:

- the development of our drug candidates, including when we expect to undertake, initiate and complete clinical trials of our product candidates;
- the anticipated timing of regulatory filings;
- the regulatory approval of our drug candidates;
- the anticipated timing of product revenues and the commercial availability of our drug candidates;
- our use of clinical research organizations and other contractors;
- our ability to find collaborative partners for research, development and commercialization of potential products;
- our ability to market any of our products;
- our history of operating losses;
- our expectations regarding our costs and expenses;
- our anticipated capital requirements and estimates regarding our needs for additional financing;
- our ability to compete against other companies and research institutions;
- our ability to secure adequate protection for our intellectual property;
- our intention to vigorously defend against a purported securities class action lawsuit; derivative lawsuits and a defamation lawsuit;
- our ability to attract and retain key personnel; and
- our ability to obtain adequate financing.

These statements are often, but not always, made through the use of words or phrases such as “anticipate,” “estimate,” “plan,” “project,” “continuing,” “ongoing,” “expect,” “believe,” “intend” and similar words or phrases. Accordingly, these state involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Discussions containing these forward-looking statements may be found throughout this Quarterly Report on Form 10-Q, including, in Part I, the section entitled “Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.” These forward-looking statements involve risks and uncertainties, including the risks discussed in Part I, Item 1A. “Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2015 and Part II, Item 1A. “Risk Factors” of this Quarterly Report on Form 10-Q that could cause our actual results to differ materially from those in the forward-looking statements. Such risks should be considered in evaluating our prospects and future financial performance. We undertake no obligation to update the forward-looking statements or to reflect events or circumstances after the date of this document.

Part I – FINANCIAL INFORMATION

Item 1. Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share data)

	March 31, 2016 (unaudited)	December 31, 2015 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 78,219	$ 31,569
Marketable securities	102,995	184,320
Prepaid expenses and other, current	8,143	7,660
Total current assets	189,357	223,549
Property and equipment, net	2,219	2,383
Prepaid expenses and other, long-term	9,284	9,597
Restricted cash	4,314	4,313
Total assets	$ 205,174	$ 239,842
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 24,837	$ 17,803
Accrued expenses	14,068	14,639
Total current liabilities	38,905	32,442
Deferred rent	1,326	1,393
Total liabilities	40,231	33,835
Commitments and contingencies (Note 8 - Subsequent Events)		
Stockholders' equity:		
Common stock - $.0001 par value; 100,000,000 shares authorized; 32,493,092 shares issued and outstanding at March 31, 2016 and 32,466,842 issued and outstanding at December 31, 2015	3	3
Additional paid-in capital	756,383	726,651
Accumulated other comprehensive income (loss)	29	(147)
Accumulated deficit	(591,472)	(520,500)
Total stockholders' equity	164,943	206,007
Total liabilities and stockholders' equity	$ 205,174	$ 239,842

See Accompanying Notes to the Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands except share and per share data)

(unaudited)

	For the Three Months Ended March 31,	
	2016	2015
Operating expenses:		
General and administrative	$11,039	$7,871
Research and development	60,207	44,728
Totals	71,246	52,599
Loss from operations	(71,246)	(52,599)
Other (expenses) income:		
Interest income	282	123
Other (expenses) income	(8)	22
Totals	274	145
Net loss	$(70,972)	$(52,454)
Net loss applicable to common stock	$(70,972)	$(52,454)
Net loss per common share—basic and diluted	$(2.19)	$(1.66)
Weighted-average common shares outstanding—basic and diluted	32,478,408	31,588,315

See Accompanying Notes to the Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

(unaudited)

	For the Three Months Ended March 31,	
	2016	2015
Net loss	$(70,972)	$(52,454)
Other comprehensive loss		
Unrealized gain on available-for-sale securities	176	6
Comprehensive loss	$(70,796)	$(52,448)

See Accompanying Notes to the Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

(in thousands except share data)

(unaudited)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive Income	Accumulated	
	Shares	Amount	Capital	(Loss)	Deficit	Total
Balance at December 31, 2015	32,466,842	$ 3	$726,651	$ (147)	$ (520,500)	$206,007
Stock-based compensation	—	—	29,510	—	—	29,510
Exercises of stock options	26,250	—	222	—	—	222
Unrealized gain on available-for-sale securities	—	—	—	176	—	176
Net loss	—	—	—	—	(70,972)	(70,972)
Balance at March 31, 2016	32,493,092	$ 3	$756,383	$ 29	$ (591,472)	$164,943

See Accompanying Notes to the Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	For the Three Months Ended March 31,	
	2016	2015
Operating activities:		
Net loss	$(70,972)	$(52,454)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	208	180
Build-out allowance received from landlord	—	179
Stock-based compensation	29,510	20,103
Changes in operating assets and liabilities:		
Prepaid expenses and other	(170)	131
Accounts payable	7,034	(2,389)
Accrued expenses	(571)	(15,975)
Accrual of deferred rent	(67)	202
Net cash used in operating activities	(35,028)	(50,023)
Investing activities:		
Purchase of property and equipment	(44)	(435)
Restricted cash	(1)	—
Expenditures for leasehold improvements	—	(179)
Purchase of available-for-sale securities	(36,768)	(104,838)
Sale/maturity of available-for-sale securities	118,269	52,769
Net cash provided by (used in) investing activities	81,456	(52,683)
Financing activities:		
Net proceeds from issuance of common stock	—	205,196
Net proceeds from exercise of options	222	14,437
Net cash provided by financing activities	222	219,633
Net increase in cash and cash equivalents	46,650	116,927
Cash and cash equivalents, beginning of period	31,569	38,539
Cash and cash equivalents, end of period	$78,219	$155,466

See Accompanying Notes to the Condensed Consolidated Financial Statements

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PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1—Business and Basis of Presentation:

Business:

Puma Biotechnology, Inc., or Puma, is a biopharmaceutical company based in Los Angeles, California with a focus on the development and commercialization of innovative products to enhance cancer care. The Company in-licenses the global development and commercialization rights to three drug candidates—PB272 (neratinib (oral)), PB272 (neratinib (intravenous)) and PB357. Neratinib is a potent irreversible tyrosine kinase inhibitor that blocks signal transduction through the epidermal growth factor receptors, HER1, HER2 and HER4. Currently, the Company is primarily focused on the development of the oral version of neratinib, and its most advanced drug candidates are directed at the treatment of HER2-positive breast cancer. The Company believes that neratinib has clinical application in the treatment of several other cancers as well, including non-small cell lung cancer and other tumor types that over-express or have a mutation in HER2.

In November 2012, the Company established and incorporated Puma Biotechnology Ltd., a wholly owned subsidiary, for the sole purpose of serving as Puma's legal representative in the United Kingdom and the European Union in connection with Puma's clinical trial activity in those countries.

Basis of Presentation:

The Company is initially focused on developing neratinib for the treatment of patients with human epidermal growth factor receptor type 2, or HER2-positive, breast cancer, HER2 mutated non-small cell lung cancer, HER2-negative breast cancer that has a HER2 mutation and other solid tumors that have an activating mutation in HER2. The Company has reported a net loss of approximately $71.0 million and negative cash flows from operations of approximately $35.0 million for the three months ended March 31, 2016. Management believes that the Company will continue to incur net losses and negative net cash flows from operating activities through the drug development process.

The accompanying unaudited condensed consolidated interim financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP, pursuant to the rules and regulations of the Securities and Exchange Commission, or the SEC, for interim financial information. Accordingly, the unaudited condensed consolidated financial statements do not include all information and footnotes required by GAAP for complete annual financial statements. In the opinion of management, the accompanying unaudited condensed consolidated interim financial statements reflect all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation. Interim operating results are not necessarily indicative of results that may be expected for the year ending December 31, 2016, or for any subsequent period. These unaudited condensed consolidated interim financial statements should be read in conjunction with the Company's audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2015. The condensed consolidated balance sheet at December 31, 2015, has been derived from the audited consolidated financial statements included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2015.

The Company's continued operations will depend on its ability to raise funds through various potential sources, such as equity and debt financing. Through March 31, 2016, the Company's financing was primarily through public offerings of Company common stock and private equity placements. Given the current and desired pace of clinical development of its product candidates, management believes that the cash and cash equivalents and marketable securities on hand at March 31, 2016, are sufficient to fund clinical development through 2016 and into 2017. The Company may need additional financing until it can achieve profitability, if ever. There can be no assurance that additional capital will be available on favorable terms or at all or that any additional capital that the Company is able to obtain will be sufficient to meet its needs. If it is unable to raise additional capital, the Company could likely be forced to curtail desired development activities, which will delay the development of its product candidates.

Note 2—Significant Accounting Policies:

The significant accounting policies followed in the preparation of these condensed consolidated financial statements are as follows:

Use of Estimates:

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America, or GAAP, requires management to make estimates and assumptions that affect reported amounts of assets and liabilities, and disclosure of contingent assets and liabilities at the date of the balance sheet, and reported amounts of expenses for the period presented. Accordingly, actual results could differ from those estimates. Significant estimates include accrued expenses for the

cost of services provided by consultants who manage clinical trials and conduct research and clinical trials on behalf of the Company that are billed on a delayed basis. As the actual costs become known, the Company adjusts its estimated cost in that period. The value of stock-based compensation includes estimates based on future events, which are difficult to predict. It is at least reasonably possible that a change in the estimates used to record accrued expenses and to value the stock-based compensation will occur in the near term.

Principles of Consolidation:

The condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All significant intercompany balances and transactions have been eliminated in consolidation.

Cash and Cash Equivalents:

The Company considers all highly liquid investments with original maturities of three months or less to be cash equivalents. Cash equivalents are carried at cost, which approximates fair value.

Investment Securities:

The Company classifies all investment securities (short term and long term) as available-for-sale, as the sale of such securities may be required prior to maturity to implement management's strategies. These securities are carried at fair value, with the unrealized gains and losses reported as a component of accumulated other comprehensive income (loss) in stockholders' equity until realized. Realized gains and losses from the sale of available-for-sale securities, if any, are determined on a specific identification basis. A decline in the market value of any available-for-sale security below cost that is determined to be other than temporary results in a revaluation of its carrying amount to fair value. The impairment is charged to earnings and a new cost basis for the security is established. Premiums and discounts are amortized or accreted over the life of the related security as an adjustment to yield using the straight-line method. Interest income is recognized when earned.

Assets Measured at Fair Value on a Recurring Basis:

Accounting Standards Codification, or "ASC," 820, Fair Value Measurement, or ASC 820, provides a single definition of fair value and a common framework for measuring fair value as well as new disclosure requirements for fair value measurements used in financial statements. Under ASC 820, fair value is determined based upon the exit price that would be received by a company to sell an asset or paid by a company to transfer a liability in an orderly transaction between market participants, exclusive of any transaction costs. Fair value measurements are determined by either the principal market or the most advantageous market. The principal market is the market with the greatest level of activity and volume for the asset or liability. Absent a principal market to measure fair value, the Company uses the most advantageous market, which is the market from which the Company would receive the highest selling price for the asset or pay the lowest price to settle the liability, after considering transaction costs. However, when using the most advantageous market, transaction costs are only considered to determine which market is the most advantageous and these costs are then excluded when applying a fair value measurement. ASC 820 creates a three-level hierarchy to prioritize the inputs used in the valuation techniques to derive fair values. The basis for fair value measurements for each level within the hierarchy is described below, with Level 1 having the highest priority and Level 3 having the lowest.

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs are observable in active markets.

Level 3: Valuations derived from valuation techniques in which one or more significant inputs are unobservable.

Following are the major categories of assets measured at fair value on a recurring basis as of March 31, 2016 and December 31, 2015, using quoted prices in active markets for identical assets (Level 1), significant other observable inputs (Level 2), and significant unobservable inputs (Level 3) (in thousands):

March 31, 2016	Level 1	Level 2	Level 3	Total
Cash equivalents	$76,429	$—	$ —	$76,429
Commercial paper	—	14,932	—	14,932
Marketable securities - U.S. government	—	17,546	—	17,546
Marketable securities - corporate bonds	—	70,517	—	70,517
	$76,429	$102,995	$ —	$179,424

December 31, 2015	Level 1	Level 2	Level 3	Total
Cash equivalents	$29,166	$—	$ —	$29,166
Commercial paper	—	2,996	—	2,996
Marketable securities - U.S. government	—	11,500	—	11,500
Marketable securities - corporate bonds	—	169,824	—	169,824
	$29,166	$184,320	$ —	$213,486

The Company’s investments in commercial paper, corporate bonds and U.S. government securities are exposed to price fluctuations. The fair value measurements for commercial paper, corporate bonds and U.S. government securities are based upon the quoted prices of similar items in active markets multiplied by the number of securities owned, exclusive of any transaction costs and without any adjustments to reflect discounts that may be applied to selling a large block of securities at one time.

Concentration of Risk:

Financial instruments, which potentially subject the Company to concentrations of credit risk, principally consist of cash and cash equivalents. The Company’s cash and cash equivalents in excess of the Federal Deposit Insurance Corporation and the Securities Investor Protection Corporation insured limits at March 31, 2016, were approximately $82.3 million. The Company does not believe it is exposed to any significant credit risk due to the quality of the financial instruments in which the money is held. Pursuant to the Company’s internal investment policy, investments must be rated A-1/P-1 or better by Standard and Poor’s Corporation and Moody’s Investors Service at the time of purchase.

Property and Equipment:

Property and equipment are recorded at cost and depreciated over estimated useful lives ranging from three to five years using the straight-line method. Leasehold improvements are recorded at cost and amortized over the shorter of their useful lives or the term of the lease by use of the straight-line method. Maintenance and repair costs are charged to operations as incurred.

The Company assesses the impairment of long-lived assets, primarily property and equipment, whenever events or changes in business circumstances indicate that carrying amounts of the assets may not be fully recoverable. When such events occur, management determines whether there has been impairment by comparing the asset’s carrying value

with its fair value, as measured by the anticipated undiscounted net cash flows of the asset. Should impairment exist, the asset is written down to its estimated fair value. The Company has not recognized any impairment losses through March 31, 2016.

Research and Development Expenses:

Research and development expenses are charged to operations as incurred. The major components of research and development costs include clinical manufacturing costs, clinical trial expenses, consulting and other third-party costs, salaries and employee benefits, stock-based compensation expense, supplies and materials, and allocations of various overhead costs. Clinical trial expenses include, but are not limited to, investigator fees, site costs, comparator drug costs, and clinical research organization, or CRO, costs. In the normal course of business, the Company contracts with third parties to perform various clinical trial activities in the ongoing development of potential products. The financial terms of these agreements are subject to negotiation and variations from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients and the completion of portions of the clinical trial or similar conditions. The Company’s accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial sites, cooperative groups and CROs. The objective of the Company’s accrual policy is to match the recording of expenses in the condensed consolidated financial statements to the actual services received and efforts expended. As actual costs become known, the Company adjusts its accruals in that period.

In instances where the Company enters into agreements with third parties for clinical trials and other consulting activities, upfront amounts are recorded to prepaid expenses and other in the accompanying condensed consolidated balance sheets and expensed as services are performed or as the underlying goods are delivered. If the Company does not expect the services to be rendered or goods to be delivered, any remaining capitalized amounts for non-refundable upfront payments are charged to expense immediately. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments and payments upon the completion of milestones or receipt of deliverables.

Costs related to the acquisition of technology rights and patents for which development work is still in process are charged to operations as incurred and considered a component of research and development costs.

Stock-Based Compensation:

Stock option awards:

ASC 718, Compensation — Stock Compensation, or ASC 718, requires the fair value of all share-based payments to employees, including grants of stock options, to be recognized in the statement of operations over the requisite service period. Under ASC 718, employee option grants are generally valued at the grant date and those valuations do not change once they have been established. The fair value of each option award is estimated on the grant date using the Black-Scholes Option Pricing Method. As allowed by ASC 718 for companies with a short period of publicly traded stock history, the Company's estimate of expected volatility is based on the average expected volatilities of a sampling of seven companies with similar attributes to the Company, including industry, stage of life cycle, size and financial leverage. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant valuation. Option forfeitures are calculated when the option is granted to reduce the option expense to be recognized over the life of the award and updated upon receipt of further information as to the amount of options expected to be forfeited. The option expense is "trued-up" upon the actual forfeiture of a stock option grant. Due to its limited history, the Company uses the simplified method to determine the expected life of the option grants.

Performance shares:

The performance shares are valued on the grant date and the fair value of the performance award is equal to the market price of the Company's common stock on the grant date. The performance share expense is recognized based on the Company's estimate of a range of probabilities that the Company's closing common stock price on the vesting dates will be lower or higher than the Company's common stock price on the grant date. Based on the range of probabilities, the expense is calculated and recognized over the three-year vesting period.

Net Loss per Common Share:

Basic net loss per common share is computed by dividing net loss applicable to common stockholders by the weighted average number of common shares outstanding during the periods presented as required by ASC 260, Earnings per Share. Diluted earnings per common share are the same as basic earnings per common share because the assumed exercise of the Company's outstanding options are anti-dilutive. For the three months ended March 31, 2016, potentially dilutive securities excluded from the calculations were 5,675,393 shares issuable upon exercise of options, 9,469 shares issuable as performance awards and 2,116,250 shares issuable upon exercise of a warrant. For the three months ended March 31, 2015, potentially dilutive securities excluded from the earnings per common share calculation were 3,832,073 issuable upon exercise of options, 18,942 issuable as performance shares and 2,116,250 shares issuable upon exercise of a warrant.

Deferred Rent:

The Company has entered into operating lease agreements for its corporate offices in Los Angeles and South San Francisco that contain provisions for future rent increases, leasehold improvement allowances and rent abatements. The Company records monthly rent expense equal to the total of the payments due over the lease term, divided by the number of months of the lease term. The difference between the rent expense recorded and the amount paid is credited or charged to deferred rent, which is reflected as a separate line item in the accompanying condensed consolidated balance sheets. Additionally, the Company recorded as deferred rent the cost of the leasehold improvements paid by the landlord, which is amortized on a straight-line basis over the term of the lease.

Issuance of Common Stock Upon Exercise of Stock Option Grants:

When a stock option grant is exercised, the Company notifies its transfer agent to release the required number of common stock shares from the reserve for the Company’s 2011 Incentive Award Plan. The Company records the transaction for the cash received and the issuance of common shares. Should there be a delay in the cash receipts due to the settlement period, the Company records a receivable from the exercise of an option as part of stockholders’ equity on the condensed consolidated balance sheet.

Recently Issued Accounting Standards:

In January 2016, the FASB issued ASU No. 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities, which eliminates the requirement for public companies to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet. Additionally, the standard requires public entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes. Furthermore, the standard requires presentation of financial assets and liabilities by measurement category and form of financial asset on the balance sheet or accompanying notes to the financial statements. The standard is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early application is permitted. We are currently evaluating the impact of adoption on our financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases, which increases transparency and comparability among organizations by requiring recognition of lease assets and lease liabilities on the balance sheet and disclosure of key information about leasing arrangements. The standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. We are currently evaluating the impact of adoption on our financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Compensation – Stock Compensation: Improvements to Employee Share-Based Payment Accounting, which is intended to simplify several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The standard is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early application is permitted. We are currently evaluating the impact of adoption on our financial statements.

Note 3—Prepaid Expenses and Other:

Prepaid expenses and other consisted of the following (in thousands):

	March 31, 2016	December 31, 2015
Current:		
CRO services	$ 3,133	$ 2,969
Other clinical development	2,204	2,309
Insurance	852	1,138
Other	1,954	1,244
	8,143	7,660
Long-term:		
CRO services	6,045	5,754
Other clinical development	2,466	3,005
Insurance	90	87
Other	683	751
	9,284	9,597
Totals	$ 17,427	$ 17,257

Note 4—Property and Equipment:

Property and equipment consisted of the following (in thousands):

Property and Equipment:	March 31, 2016	December 31, 2015
Leasehold improvements	$ 1,502	$ 1,502
Computer equipment	1,690	1,646
Telephone equipment	169	169
Furniture and fixtures	1,167	1,167
	4,528	4,484
Less: accumulated depreciation and amortization	(2,309)	(2,101)
Totals	$ 2,219	$ 2,383

Note 5—Accrued Expenses:

Accrued expenses consisted of the following (in thousands):

	March 31, 2016	December 31, 2015
Accrued CRO services	$ 7,331	$ 8,436
Accrued other clinical development	2,706	3,618
Accrued legal fees	551	443
Accrued compensation	3,342	1,970
Other	138	172
Totals	$ 14,068	$ 14,639

Accrued CRO services represent the Company's estimate of such costs and will be adjusted in the period the actual costs become known. Accrued compensation includes estimated bonus and earned but unused vacation for full-time employees. When actual performance bonuses are paid out to employees, the bonus expense will be adjusted to reflect the actual expense for the year. Additionally, vacation is accrued at the rate the employee earns vacation and reduced as vacation is used by the employee.

Note 6—Stockholders' Equity:

Stock-Based Compensation:

The Company's 2011 Incentive Award Plan, or the 2011 Plan, was adopted by the Board of Directors on September 15, 2011. Pursuant to the 2011 Plan, the Company may grant incentive stock options and nonqualified stock options, as well as other forms of equity-based compensation. Incentive stock options may be granted only to employees, while consultants, employees, officers and directors are eligible for the grant of nonqualified options under the 2011 Plan. The maximum term of stock options granted under the 2011 Plan is 10 years. The exercise price of incentive stock options granted under the 2011 Plan must be at least equal to the fair value of such shares on the date of grant. Through March 31, 2016, a total of 10,529,412 shares of the Company's common stock have been reserved for issuance under the 2011 Plan.

Employee stock-based compensation for the three months ended March 31, 2016 and 2015 were as follows (in thousands, except share and per share data):

	Three Months Ended March 31,	
	2016	2015
Stock-based compensation:		
Options -		

Research and development, or R&D	$23,556	$15,254
General and administrative, or G&A	5,882	4,704
Performance shares - R&D	72	145
Total stock-based compensation expense	$29,510	$20,103
Impact on basic and diluted net loss per share	$0.91	$0.64
Weighted average shares (basic and diluted)	32,478,408	31,588,315

Performance Shares:

During January 2014, performance share awards that provide for a maximum of 28,411 common stock shares to be issued were granted to certain employees. These shares vest over three years on the first, second and third anniversary of December 15, 2013. On each vesting date, if the Company's closing common stock price is equal to $102.46 per share, one-third of the 28,411 shares will be awarded. If the Company's closing common stock price is either lesser or greater than $102.46 per share, the number of common stock shares to be issued will be adjusted to be less than one-third of the 28,411 shares. No shares will be awarded if the Company's closing common stock price is less than $47.53 per share at the vesting dates. The performance shares are valued on the grant date and the fair value of the performance award is equal to the market price of the Company's common stock on the grant date. The performance share expense is recognized based on the Company's estimate of a range of probabilities that the Company's closing common stock price will be lower or higher than $102.46 on the vesting dates. Based on the range of probabilities, the expense is calculated and recognized over the three-year vesting period. On December 15, 2015, the second vesting occurred and the calculations were performed. As a result, 6,530 shares of common stock were issued to the employees and 2,943 performance shares were cancelled. The third and final vesting event will occur on December 15, 2016.

Performance shares	Shares	Weighted Average Grant-Date Fair Value
Nonvested shares at December 31, 2015	9,469	$ 102.46
Granted	—	—
Vested/Issued	—	—
Cancelled	—	—
Nonvested shares at March 31, 2016	9,469	$ 102.46

Stock Options:

The fair value of options granted to employees was estimated using the Black-Scholes Option Pricing Method (see Note 2—Significant Accounting Policies) with the following weighted-average assumptions used during the three months ended March 31, 2016 and 2015:

	2016	2015
Dividend yield	0.0 %	0.0 %
Expected volatility	66.1%	63.1%
Risk-free interest rate	1.6 %	1.6 %
Expected life in years	5.85	5.85

Activity with respect to options granted under the 2011 Plan is summarized as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2015	5,542,285	$ 105.59	8.6	$ 87,632
Granted	249,750	$ 60.82		
Forfeited	(89,392)	$ 121.08		
Exercised	(26,250)	$ 8.46		$ 920
Expired	(1,000)	$ 106.41		
Outstanding at March 31, 2016	5,675,393	$ 103.83	8.4	$ 17,190
Nonvested at March 31, 2016	3,433,496	$ 118.33	9.2	$ —
Exercisable at March 31, 2016	2,241,897	$ 81.62		